

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BOSTON SCIENTIFIC CORPORATION)	<u>REDACTED PUBLIC VERSION</u>
and BOSTON SCIENTIFIC SCIMED, INC.,)	
)	
Plaintiffs,)	
)	C.A. No. 18-1869-CFC-CJB
v.)	
)	
MICRO-TECH ENDOSCOPY USA INC.,)	
MICRO-TECH (NANJING) CO., LTD., and)	
HENRY SCHEIN INC.,)	
)	
Defendants.)	

**LETTER TO THE HONORABLE COLM F. CONNOLLY FROM ANDREW C. MAYO
REGARDING REQUEST FOR CLARIFICATION OF
PRIOR CLAIM CONSTRUCTION DECISION**

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Dated: November 2, 2020

November 2, 2020

VIA CM/ECF

The Honorable Colm F. Connolly
United States District Court
for the District of Delaware
844 N. King Street
Wilmington, DE 19801

CONFIDENTIAL:
FILED UNDER SEAL

Re: Boston Scientific Corporation, et al. v. Micro-Tech Endoscopy USA Inc., et al., C.A. No. 18-1869-CFC-CJB

Dear Judge Connolly:

Defendants Micro-Tech Endoscopy USA Inc., Micro-Tech (Nanjing) Co., Ltd., and Henry Schein Inc. write to respectfully request the Court's guidance regarding two claim constructions adopted by the Court that we respectfully submit should resolve all infringement claims on two of the three patents in suit, USP Nos. 7,094,245 and 9,980,725.

In short, Plaintiffs' Final Infringement Contentions ("FICs") and recently served expert reports rely on infringement theories that are directly inconsistent with Your Honor's claim construction rulings. (D.I. 140) *On the '245 patent*, Plaintiffs have attempted to side-step the Court's construction of "breakable link . . . adapted to be broken" by arguing that Defendants' accused products are subject to "plastic deformation," when Your Honor specifically ruled that "deformation" cannot satisfy the Court's claim construction. *On the '725 patent*, Plaintiffs assert that the accused products meet the Court's construction of "connecting member," which requires "a tension member" that "biases the clip arms to an open configuration," even though the clip arms in those products have no "bias" (open or closed) and cannot meet the limitation, as construed.

We attempted to resolve these matters by filing a motion to strike the FICs with Magistrate Judge Burke (D.I. 168). Judge Burke concluded, however, that he was: (1) "not certain" whether the "plastic deformation" alleged in the FICs is "the exact same thing" as the "deformation" Your Honor ruled could not meet the '245 patent limitation; and (2) "in no position to definitively conclude that Plaintiffs' interpretation of the word 'bias' in the District Court's claim construction is the wrong one," noting it might present "a further issue for claim construction." (D.I. 205). Judge Burke thus concluded that resolution of Defendants' challenges to Plaintiffs' FICs required either clarification or a more thorough understanding of

Your Honor's claim constructions. The need for input from Your Honor was confirmed by Plaintiff's recent expert report on infringement, which relies and elaborates on the FIC's infringement theories that are contrary to the Court's claim construction rulings on the '245 and '725 patents.

We recognize that one option is to proceed through expert discovery and to address these issues at summary judgment. However, in the hope of avoiding the expense of competing expert reports that turn on claim constructions, and then burdening the Court with voluminous summary judgment briefing, we respectfully request that the Court issue an order clarifying whether its claim construction rulings preclude Plaintiff's "plastic deformation" and "bias" infringement theories.

I. "Breakable link....adapted to be broken"

Your Honor adopted Defendants' proposed construction of "a component of the device designed to mechanically fail by fracturing at a predetermined tensile load" and rejected plaintiffs' position that this term meant a mere "connection" between components that could be "broken" upon deformation of one of the components":

I find, however, that the specification does not establish that the breakable link can break through deformation. The claims reveal that the patent differentiates between the deformable J-hook and the breakable link claimed in claim 1.

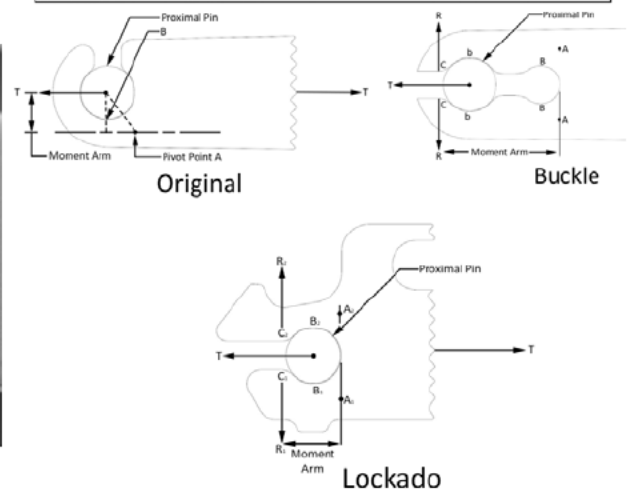
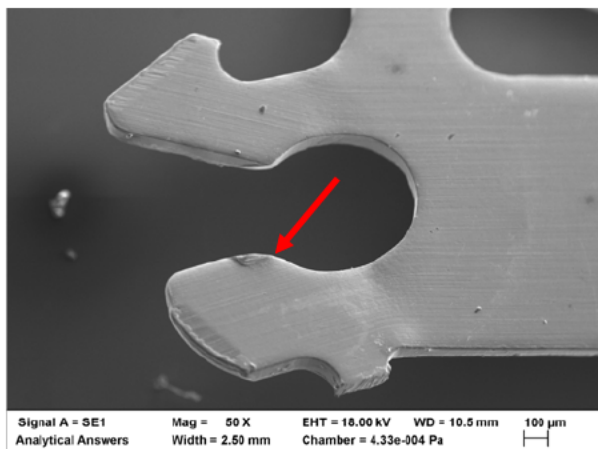
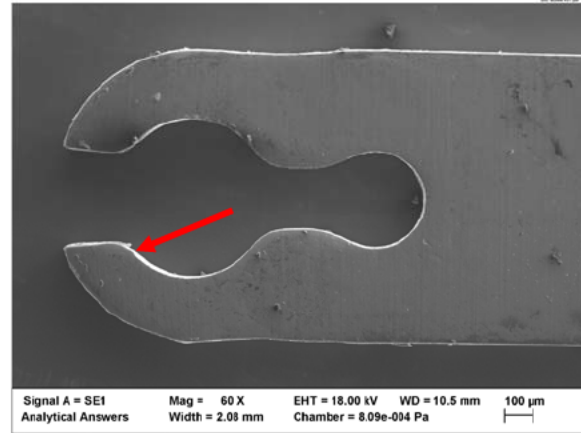
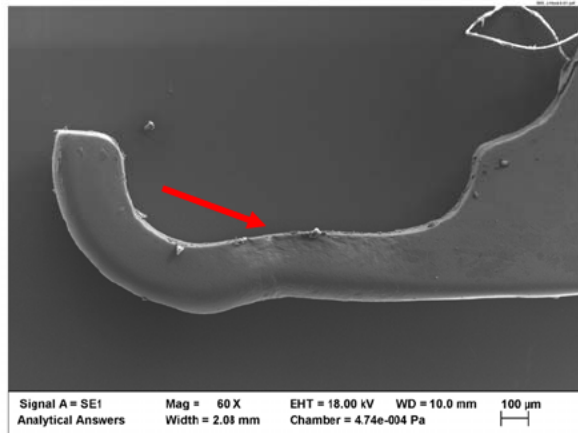
D.I. 169, p. 2, and Markman Hearing Tr. at 32:13-17. Yet Plaintiffs' FICs and expert report rely on the position rejected by the Court. Leinsing Report at ¶¶76-77 (Ex. A). Defendants respectfully submit that Your Honor's ruling that "the specification does not establish that the breakable link can break through deformation" should preclude plaintiffs from continuing to contend that they can establish infringement simply by using the term "plastic deformation." Your Honor's construction that the accused component must be "designed to mechanically fail by fracturing" makes clear that fracturing cannot be merely incidental to the deformation of a component, as opposed to the manner in which the component is designed to break and mechanically fail.

That Plaintiffs' "plastic deformation" infringement theory disregards your Honor's claim construction ruling is made clear by the following SEM micrographs of post-deployment hooks (one from each of the three configurations of the accused products) that Plaintiffs' expert rely on to show "a component of the device designed to mechanically fail by *fracturing* at a predetermined tensile load":

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Plaintiffs' expert asserts that the area identified with red arrows in each hook is a breakable link designed to mechanically fail by fracturing. Even at 50-110 times magnification under a scanning electron microscope, nothing has fractured, much less failed mechanically as a result of fracturing at a predetermined tensile load (see also plaintiffs' diagram of each undeployed hook shown above in the lower right). This is precisely what the Court ruled was not a "breakable link...adapted to be broken" in its claim construction rulings. The Court further found that Boston Scientific "disclaimed the scope of the term during prosecution of the '245 patent's counterpart," in part through its argument that a fracture means the component breaks into pieces, not merely deforms:

Moreover, in an opposition proceeding against the '199 European patent, Boston Scientific asserted that the claim thus requires the link to be broken wherein to break is clearly given the meaning and scope, which the term normally has in the art, i.e., that fracture of a link into two or more pieces takes place.

D.I. 169 at 34:17-22. Defendants respectfully request confirmation that deformation cannot form the basis for Plaintiffs' contentions in this case with respect to the "breakable link" limitation, regardless of whether such deformation may be accompanied by microscopic changes in the metal structure of the component that accommodates the deformation.

II. "Connecting member"

In adopting Defendants' proposed construction of "connecting member" as "a tension member that connects the clips arms to the yoke and biases the clip arms to an open configuration" (D.I. 140), Your Honor rejected Plaintiffs' position that the claim term includes any component that connects the clip to the yoke and is involved in opening and closing the clip. Nonetheless, Plaintiffs are now proceeding with infringement claims that rest on that rejected position. Defendants respectfully submit that no further construction of this term is needed, because the Court and the parties know what the term "bias" means in the '725 patent.

Plaintiffs' FICs and Infringement Expert Report identify no alleged "tension" or "bias" to an open configuration of the clip arms in the accused products. To the contrary, they state that the proximal pin (the alleged connecting member) moves with other parts to open and close the clip arms:

"It connects the clip arms to the arms of the yoke, such that forces applied to the control member put the proximal pin under load *so as to cause the clip arms to open and close* as described above." Ex. A at ¶176.

Neither the FICs nor Mr. Leinsing's report allege that the clip arms in any accused products are biased open or that the proximal pin imparts any bias or tension.

Plaintiffs further admitted to a Request for Admission (following defendants' successful motion to compel a response) that it is in fact the *distal pin*, if anything, that plaintiffs contend "forces the clip arms... into an open configuration:"

as the clip arms (made up of the clip, i.e., the multi-legged grasping device, and the clip rails) move distally through the capsule, *the distal pin*, which is rigidly coupled to the distal end of the capsule, rides through the slots formed in the proximal section of the clip arms *to force the clip arms apart from one another into an open configuration*.

Response to RFA No. 15. Plaintiffs FICs and Infringement Expert Report are thus contradicted by their own admissions in response to this Request for Admission. Plaintiffs and their infringement expert readily understand what "bias" means with respect to a clip, as demonstrated by their own use of the term 78 times in Mr.

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Leinsing's expert report on the same patent specification in the Cook litigation, (BSC-MT-126649), see e.g.:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Nevertheless, Plaintiffs are proceeding with an infringement theory that ignore the Court's claim construction and the fact that there is no tension member in the accused products in this case that biases the arms of the accused clips to an open configuration.

* * * *

We would appreciate any guidance the Court concludes would be useful and appropriate. Should the Court wish to discuss, counsel are available at the Court's convenience.

Respectfully,

/s/ Andrew C. Mayo

Andrew C. Mayo (#5207)

ACM/nml
Attachment

cc: All Counsel of Record (via electronic mail; w/attachment)

EXHIBIT A

**REDACTED IN
ITS ENTIRETY**